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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,288	01/08/2001	Frederic Carencotte	ST-98/020	8177

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EXAMINER

OH, TAYLOR V

[REDACTED]
ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,288	CARENCOTTE ET AL.	
	Examiner T. Victor Oh	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 January 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Claim Rejections - 35 USC § 112

1. Claims 1, 3, 6, 8, 11, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 6, a phrase “ water sufficient to exhaustively extract virtually all the HMTBA present” is written. However, the terms such as “sufficient” and “virtually” are unclear to describe the metes and bounds of the claim. An appropriate correction is required.

In claims 11 and 12, a phrase “ sufficient amount of an organic solvent” is written. However, the phrase such as “sufficient amount” is unclear as to how much the organic solvent is needed to carry out the process. An appropriate correction is required.

Regarding claims 3 and 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

2. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

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explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “preferably” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 5 recites the broad recitation of the range “ greater than 0.05 ”, and the claim also recites “ preferably between 0.1 and 0.05 ” which is the narrower statement of the range/limitation.

In another instance, claim 10 recites the broad recitation “ greater than 0.3 ”, and the claim also recites “ preferably between 0.3 and 1 ” which is the narrower statement of the range/limitation.

Claims 5 and 10 are rejected on the basis of the above reasons.

3. Claim 14 provides for the use of the crystals, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

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encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 103

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deer Co.*, 383 U.S. 1, 148 USPO 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-13, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Ruest et al (U.S. 4,524,077) in view of Grendel et al (U.S. 5,498,790) and Kawabe et al (U.S. 5,763,652).

Ruest et al teaches a process of preparing 2-hydroxy-4-methylthiobutyric acid (HMBA) in which 2-hydroxy-4-methylthiobutyronitrile (HMBN) is hydrolyzed with (see col. 2 , lines 65-68) sulfuric acid (see col. 4 , lines 55-56) to produce an aqueous hydrolyzate containing HMBA and some amide (see col. 3 , lines 1-3). The hydrolyzate is further treated with a water-immiscible organic solvent such as methyl ethyl ketone, methyl isobutyl ketone (see col. 7 , lines 26-30) in a liquid-liquid extraction system to produce an extract containing HMBA, thereby recovering the HMBA (see col. 3 , lines 3-12).

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Before carrying out the extraction , the hydrolyzate is neutralized by the addition of a 28 % by weight ammonia solution; during the extraction, it is recommended that the solubility of water in the solvent is not greater than 12 % by weight (see col. 10 , lines 48-51); furthermore, in an example, the neutralized hydrolyzate (50 ml; 63 g) is contacted is contacted with methyl ethyl ketone (50 ml) and water (10 ml) for extraction of the HMBA (a ratio of amt. of solvent to neutralized hydrolyzate by weight = $60/63=0.95$) (see col. 10 , lines 48-51); in addition, the organic solvent is evaporated from the organic layer to obtain the desired product (see col. 10 , lines 63-65).

However, the instant invention differs from the Ruest et al reference that the 2-hydroxy-4-methylthiobutyric acid is crystallized by the treatment of electrodialysis and a sulfuric acid is recovered by the thermal route in order to be recycled to the hydrolysis of the HMTBN.

Grendel et al teaches a process of disposition of sulfate by-product produced in the preparation of HMBA by hydrolysis of HMBN, thereby regenerating a sulfuric acid to be used for hydrolysis of HMBN in the preparation of HMBA (see col. 1 , lines 9-15). During the process, a feed mixture obtained as a by product of the preparation of HMBA by hydrolysis of HMBN with sulfuric acid is burned in the combustion zone to produce a combustion gas containing sulfur dioxide and water, which is condensed to form the sulfuric acid (see col. 3 , lines 29-43). The regenerated the sulfuric acid is supplied to the hydrolysis step for the HMBA process (see col. 4 , lines 19-26).

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Furthermore, Kawabe et al (U.S. 5,763,652) teaches a process of producing a carboxylic acid such as 2-hydroxy-4-methylthiobutyric acid (HMBA) from a starting material of 2-hydroxy-4-methylthiobutyronitrile (HMBN)(see col. 21, lines 25-39) in various steps : hydration, hydrolysis, a recycling of ammonia, and electrodialysis (see col. 12, lines 1-20). Also, the Kawabe et al reference describes that a utilization of electrodialysis brings about an effective decomposition of a by-product salt such as an ammonium salt so that ammonia can be efficiently reused in the production of the carboxylic acid from the nitrile compound (see col. 2, lines 27-36).

Therefore, if the person having an ordinary skill in the art had desired to optimize the reaction conditions such as a recycling of ammonia by means of the electrodialysis without forming other by-products and a recycling of the sulfuric acid for the hydrolysis step for the production of HMBA, it would have been obvious for the skillful artisan in the art to have used Grendel et al's recycling sulfuric acid for the hydrolysis step and Kawabe et al's electrodialysis in the Ruest et al's process, thereby achieving a cost-effective process.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Baker et al (U.S. 4,353,924) discloses that the prepared M.A. acid contains from 0.3 to 0.5% residual mineral acid from the hydrolysis step. There are three stages in the process to prevent forming excess mineral acid in the M.A. acid by neutralization. The excess mineral acid may be neutralized (1) after hydrolysis and before dehydration,(2) after hydrolysis and before centrifuging, and (3) after centrifuging when the concentrated M.A. acid has been diluted to 87 to 90 % by weight.

Blake et al (U.S. 2,745,745) discloses a process for preparing alpha-hydroxy aliphatic carboxylic acids , particularly alpha-hydroxy-gamma-methylmercapto butyric acid. The acid is prepared by the hydrolysis of the cyanohydrin to the amide in the presence of an inert organic liquid such as carbon tetrachloride, and concentrated sulfuric acid or hydrochloric acid is used for the hydrolysis at a temperature 75° C. The salts of the acid improves the efficiency of feed utilization by poultry when incorporated in the poultry feed lacking in free methionine.

Matsuoka (U.S. 5,386,056) discloses a process for producing 2-hydroxy-4-methylthiobutanoic acid. The following three steps are involved in the process. The first step is the hydrolysis of 2-hydroxy-4-methylthiobutyronitrile to 2-hydroxy-4-methylthiobutanamide,

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the second step is related to the reaction of 2-hydroxy-4-methylthiobutanamide with methyl formate to produce the methyl 2-hydroxy-4-methylthiobutanoate, and the last step is the hydrolysis of the methyl 2-hydroxy-4-methylthiobutanoate to obtain 2-hydroxy-4-methylthiobutanoic acid.

Takano (U.S. 4,579,962) discloses enhanced compositions of 2-hydroxy-4-methylthiobutanoic acid with sodium, potassium, magnesium, and zinc, which have a greater molar ratios of HMBA equivalency to metallic cations than the ionic salts.

Cummins (U.S. 4,310,690) discloses a process for preparing the calcium salt of alpha-hydroxy-gamma-methylmercaptopbutyric acid. The following steps are involved in the process. The alpha-hydroxy-gamma-methylmercaptopbutyronitrile is hydrolyzed with hydrochloric acid to form alpha-hydroxy-gamma-methylmercaptopbutyric acid, which is mixed with aqueous lime slurry at a pH 8.5 to 11.0 at a temperature 45⁰ to 90⁰ C., which is subsequently treated with filtration and purification steps to obtain the product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

PJ
2/22/02



PAUL J. KILLOS
PRIMARY EXAMINER